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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,797	07/15/2004	Eisaku Oshiman	10921.0234USWO	6594

52835 7590 08/20/2007
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EXAMINER

EDWARDS, LYDIA E

ART UNIT	PAPER NUMBER
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1709

MAIL DATE	DELIVERY MODE
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08/20/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/501,797

Applicant(s)

OSHIMAN ET AL.

Examiner

Lydia Edwards

Art Unit

1709

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 July 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 7/15/2004, 7/19/2006.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 19 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding Claim 19, the examiner is unclear as to what a "conductor" is.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Ogura (JP 05126792).

Regarding Claim 1, Ogura ('792) discloses a temperature detecting analytical device comprising a mounting portion for mounting an analytical tool capable of outputting information for computation, a computation unit for conducting computation for analyzing a sample based on said information for computation, and a temperature detection unit for outputting the temperature information, wherein said temperature detection unit is disposed in said mounting portion (paragraphs 19, 24, 25).

Regarding Claim 2, Ogura ('792) discloses a temperature detecting analytical device which further comprises a temperature correction unit for correcting the computation results

Art Unit: 1709

obtained in said computation unit, based on said temperature information (paragraphs 27 and 31).

Regarding Claim 3, Ogura ('792) discloses a temperature detecting analytical device wherein said temperature detection unit comprises a contact type temperature sensor (paragraph 19).

Regarding Claim 4, Ogura ('792) discloses a temperature detecting analytical device wherein said temperature detection unit comprises a thermally conductive portion having a contact surface to be brought into contact with said temperature sensor and said analytical tool (paragraph 19).

Regarding Claim 9, Ogura ('792) discloses wherein said temperature detection unit comprises a contact type temperature sensor, and the temperature sensor is disposed so as to be in direct contact with said analytical tool when said analytical tool is mounted on said mounting portion (paragraph 19 and figure 2).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5-8, 10, 11 and 12-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogura (JP 05126792) in view of Bhullar et al. (US 6780296).

Regarding Claim 5, Ogura ('792) does not disclose a thermally conductive portion is formed from a material with a thermal conductivity of higher than 0.10 cal/(C°-cm-sec).

Bhullar ('296) discloses a heat conducting layer that has a thermal conductivity of at least 200 W/m-K which is equivalent to 0.477 cal/C°-cm-sec (Col 3, lines 23-31).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Ogura with a heat conducting layer that has a thermal conductivity of higher than 0.10 cal/(C°-cm-sec) as taught by Bhullar to improve the overall thermal conductivity of the sensor strip.

Art Unit: 1709

Regarding Claim 6, Ogura ('792) does not disclose a thermally conductive portion is formed from a material with a thermal conductivity of higher than $0.15 \text{ cal/(}^{\circ}\text{C-cm-sec.)}$

Bhullar ('296) discloses a heat conducting layer that has a thermal conductivity of at least 200 W/m-K which is equivalent to $0.477 \text{ cal/}^{\circ}\text{C-cm-sec}$ (Col 3, lines 23-31).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Ogura with a heat conducting layer that has a thermal conductivity of higher than $0.15 \text{ cal/(}^{\circ}\text{C-cm-sec)}$ as taught by Bhullar to improve the overall thermal conductivity of the sensor strip.

Regarding Claim 7, Ogura ('792) does not disclose a thermally conductive portion is formed from iron, copper, aluminum, alloys containing at least one of those metals as the main component, and ceramics.

Bhullar ('296) discloses a thermally conductive portion is formed from copper or aluminum, and ceramics (Col 3, lines 23-40).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Ogura with a thermally conductive portion is formed from copper or aluminum and ceramics as taught by Bhullar to improve the overall thermal conductivity of the sensor strip.

Regarding Claim 8, Ogura ('792) does not disclose wherein said temperature sensor and said thermally conductive portion are disposed in said mounting portion in which they are sealed with a resin package.

However, Bhullar ('296) disclose a means for laminating the heat conductive layer and an electrode substrate together of which the examiner deems analogous to sealing the temperature sensor and said thermally conductive portion together with a resin package (Col 4, lines 14-61).

Art Unit: 1709

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Ogura with a laminating means as taught by Bhullar in order to provide adequate support to the sensor.

Regarding Claim 10, Ogura ('792) does not disclose wherein said temperature detection unit comprises a non-contact type temperature sensor.

Bhullar ('296) discloses wherein said temperature detection unit comprises a non-contact type temperature sensor (Col 2, lines 55-63).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Ogura with a non-contact type temperature sensor as taught by Bhullar to provide an alternate means.

Regarding Claim 11, Ogura ('792) does not specifically disclose, wherein when an analytical tool comprising a reagent portion is used as said analytical tool, said temperature detection unit is disposed so as to be located in the region directly below or in the region directly above said reagent portion when said analytical tool is mounted on said mounting portion.

Bhullar ('296) discloses wherein when an analytical tool comprising a reagent portion is used as said analytical tool, said temperature detection unit is disposed so as to be located in the region directly below or in the region directly above said reagent portion when said analytical tool is mounted on said mounting portion (Col 2, lines 39-42).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Ogura with a reagent portion as taught by Bhullar to provide a means to measure glucose in a human blood sample.

Regarding Claim 12, Ogura ('792) discloses a temperature detecting analytical device according to claim 11, wherein said reagent portion comprises an enzyme (paragraph 40).

Art Unit: 1709

Regarding Claim 13, Ogura ('792) does not disclose, wherein said enzyme has a catalytic action with respect to the oxidation reaction of glucose.

Bhullar ('296) discloses wherein said enzyme has a catalytic action with respect to the oxidation reaction of glucose (Col 5, lines 29-13; Col 6, lines 1-9; and table 1).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Ogura with an enzyme that has a catalytic action as taught by Bhullar to facilitate electron transfer.

Regarding Claim 14, Ogura ('792) does not specifically disclose, wherein said analytical tool is disposable.

Bhullar ('296) discloses wherein said analytical tool is disposable (Col 6, lines 14-15 and figure 6).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Ogura with a disposable means as taught by Bhullar to facilitate quick and accurate detection.

Regarding Claim 15, Ogura ('792) does not specifically disclose wherein said mounting portion comprises an insertion portion for inserting the end portion of said analytical tool and a table portion for installing said analytical tool, said temperature detection unit being disposed in said table portion.

Bhullar ('296) discloses wherein said mounting portion comprises an insertion portion for inserting the end portion of said analytical tool and a table portion for installing said analytical tool, said temperature detection unit being disposed in said table portion (figure 6).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Ogura with a insertion portion and a table portion as taught by Bhullar to provide an easy contact means.

Art Unit: 1709

Regarding Claim 16, Ogura ('792) does not specifically disclose 15, wherein said table portion protrudes to the side of said analytical device.

Bhullar ('296) discloses wherein said table portion protrudes to the side of said analytical device (figure 6).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Ogura with a table portion that protrudes as taught by Bhullar to provide an easy contact means.

Claim 17-19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ogura (JP 05126792) in view of Bhullar (US 6780296) in further view of Nankai et al. (US 5320732).

Regarding Claim 17, neither Ogura ('792) nor Bhullar ('296) specifically disclose, wherein a push-down portion for pushing said analytical tool down with respect to said table portion is disposed in said mounting portion.

Nankai et al. ('732) discloses a push-down portion for pushing said analytical tool down with respect to said table portion is disposed in said mounting portion (figure 1-7).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Ogura with a push-down portion as taught by Nankai et al. . to provide an indicator of assembly.

Regarding Claim 18, Ogura ('792) does not specifically disclose push-down portion but does disclose an output unit for outputting said information for computation is used as said analytical tool (Figure 1).

Bhullar ('296) does not specifically disclose push-down portion or an output unit for outputting said information for computation is used as said analytical tool.

Art Unit: 1709

Nankai et al. ('732) discloses a push-down portion (figure 1-7). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Ogura with a push-down portion as taught by Nankai et al. to provide an indicator of assembly.

Regarding Claim 19, Ogura ('792) does not specifically disclose wherein push-down portion is a plate spring formed from a conductor.

The examiner is interpreting a conductor to be an electrical conductor.

Nankai et al. ('732) discloses a push-down portion (figure 1-7).

Bhullar ('296) discloses a thermally conductive portion is formed from copper or aluminum, which are known electrical conductors (Col 3, lines 23-40).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Ogura with a push-down portion as taught by Nankai et al. to provide an indicator of assembly and a thermally conductive portion is formed from copper or aluminum and ceramics as taught by Bhullar to improve the overall thermal conductivity of the sensor strip.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lydia Edwards whose telephone number is (571) 270-3242. The examiner can normally be reached on Mon-Fri 8-5 (Alternate Fri).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on (571) 272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1709

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lydia Edwards

Examiner

Art Unit 1709

LE

Melvin Hayes
[Signature]
Primary Examiner
W1734